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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS)	
CORPORATION, NOVARTIS)	
CORPORATION, and NOVARTIS AG,)	Civil Action No.:
Plaintiffs,)	2 :12-cv-03967-SDW-MCA
)	
v.)	[Consolidated Actions]
)	
WOCKHARDT USA LLC and)	
WOCKHARDT LIMITED,)	MOTION RETURN DAY: July 15, 2013
Defendants.)	
_____)	

NOVARTIS PHARMACEUTICALS)	
CORPORATION, et al.,)	
)	
Plaintiffs,)	
)	
v.)	2:12-cv-04394-SDW-MCA
)	
SUN PHARMA GLOBAL FZE, et al.,)	
)	
Defendants.)	
_____)	
)	
NOVARTIS PHARMACEUTICALS)	
CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	2:13-cv-01028-SDW-MCA
)	
ACTAVIS LLC, et al.,)	
)	
Defendants.)	
_____)	
)	
NOVARTIS PHARMACEUTICALS)	
CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	2:13-cv-02379-SDW-MCA
)	
ACCORD HEALTHCARE INC., et al.,)	
)	
Defendants.)	
_____)	

DEFENDANTS WOCKHARDT USA LLC AND WOCKHARDT LIMITED'S
REPLY BRIEF IN SUPPORT OF APPEAL FROM MAGISTRATE
JUDGE'S ORDER GRANTING PLAINTIFFS' REQUEST FOR
LEAVE TO AMEND ASSERTED CLAIMS

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Defendants Wockhardt USA LLC and Wockhardt Ltd. (collectively, “Wockhardt”) respectfully submit this reply brief in support of their appeal from Magistrate Judge Arleo’s May 31, 2013 Order (D.I. 82) granting Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation and Novartis AG’s (collectively, “Novartis”) Motion for Leave to Amend the Disclosure of Asserted Claims.

I. INTRODUCTION

Novartis sued Wockhardt on U.S. Patent No. 8,052,987 (“the ’987 patent”) on June 27, 2012, reviewed Wockhardt’s non-infringement position, and subsequently chose not to assert any claims of that patent against Wockhardt. Novartis has no basis for re-asserting that patent against Wockhardt. *Not a single legal right regarding the ’987 patent has changed since this case began.* Thus, the Magistrate Judge’s Order, allowing Novartis to re-assert the ’987 patent must be reversed.

Novartis claims that the Magistrate Judge’s finding of good cause was proper because she found a change in legal rights, which for the first time, made it practical for Novartis to assert the ’987 patent. However, this position is wholly unsupported by the record. Novartis has *never* explained why, if it was so impractical to assert the ’987 patent, it filed suit against Wockhardt alleging infringement of the ’987 patent in June of 2012, roughly six months prior to the

issuance of U.S. Patent No. 8,324,189 (“the ’189 patent”). Nor has Novartis ever explained why it maintained that allegation for four months. The simple answer is that Novartis cannot answer these questions without exposing the fatal flaws in its good cause story. In June 2012, Novartis saw value and practicality in asserting the ’987 patent against Wockhardt, even though it *allegedly* held no belief that the ’189 patent would issue. Novartis’s own actions completely undermine the Magistrate Judge’s critical finding that it was impractical for Novartis to assert the ’987 patent until the ’189 patent issued. It was *not* impractical – it happened.

Moreover, the Magistrate Judge’s finding of impracticality was based on the presumption that assertion of the ’987 patent did not make sense until Novartis obtained patent protection for its Zometa[®] products. Again, the premise of the Magistrate Judge’s finding is contradicted by the record. Novartis alleged U.S. Patent No. 7,932,241 (“the ’241 patent”) against Wockhardt based on an ANDA submitted for a generic Zometa[®] product. The only “impracticality” was Novartis’s allegations that it had no protection for its zoledronic acid products. In light of the ’241 patent protection that Novartis already had, and anticipated having, Novartis’s story of impracticality crumbles.

This Court has heard Novartis’s work of fiction before, and despite Novartis’s protestations, it is highly relevant that this Court previously dismissed Novartis’s story stating that:

[I]t strains credibility, in my opinion, quite frankly, to say that it was only at the time that this '189 patent came around that we realized we can do anything [on the '987 patent]. *That just doesn't make sense to me*. And I don't think it's supported by the record. I don't think the dates support that. I think that's very clear.

(Mar. 1, 2013 TRO Hearing Tr. 76:23-77:3 (emphasis added).) The Magistrate Judge committed clear error by ignoring this Court's prior analysis and instead finding good cause based on facts that are flatly contradicted by the record.

The Magistrate Judge's ruling, based on an improper and conflated analysis of good cause and undue prejudice, is contrary to law. In its opposition, Novartis attempts to remedy this error by claiming that consolidation was relevant to the good cause analysis. However, Novartis's claim that good cause to amend its asserted claims to now assert the '987 patent against Wockhardt exists, simply because Novartis elected to sue several other defendants, is absurd. Nowhere in the Local Patent Rules is there a suggestion that asserting a patent against new litigants somehow creates good cause to correct a failure to continue asserting the same patent against Wockhardt. Moreover, as filing suit against additional parties is not "relevant to the merits of party's claim," such an event does not even fall within Novartis's own, inaccurate and overbroad, definition of circumstances that support a finding of good cause.

Novartis has attempted to characterize its actions as anything except for what they truly are: *a mid-case shift in litigation strategy*. Novartis's shifting

sands approach to litigation is precisely what the Local Patent Rules were enacted to prevent. The Magistrate Judge's ruling allowing Novartis's mid-case shift in litigation strategy is unsupported by the record, contrary to law, and undermines the intent of the Local Patent Rules. Accordingly, this Court should reverse the Magistrate Judge's grant of leave for Novartis to amend its Asserted Claims.

II. ARGUMENT

A. The Magistrate Judge Committed Clear Error Evaluating Good Cause

Novartis's "good cause" argument is nothing more than a weak attempt to redo its previous, binding litigation decisions by telling the same story that this Court has already deemed "unbelievable." (*See* Mar. 1, 2013 TRO Hearing Tr. 76:23-77:3.)

1. The Record Does Not Support the Finding that Asserting the '987 Patent Prior to Issuance of the '189 Patent was Impractical

All throughout its briefing to the Magistrate Judge, and at least seven times in its opposition on appeal, Novartis argues that it would be "nonsensical" and impractical for it to have asserted the '987 patent against any defendant, including Wockhardt, prior to the issuance of the '189 patent. (*See, e.g.,* Opp'n, D.I. 135, at 4, 5, 10, 12, 13; D.I. 55 at 3; D.I. 51 at 6.) Novartis's position is utter fiction, undercut by its own actions in this case.

Novartis admits that the crux of the Magistrate Judge's finding of "good cause" is the presumption that it was "nonsensical" and impractical from a

litigation perspective to pursue the '987 patent until the '189 patent issued on December 4, 2012. (Opp'n, D.I. 135, at 12.) However, the fact that Novartis asserted the '987 patent against Wockhardt in June 2012, six months prior to the issuance of the '189 patent, flatly contradicts such a finding. (*See* Compl., D.I. 1, ¶¶ 44-48.) Moreover, Novartis's story fails to explain why it elected to assert the '987 patent against Wockhardt at a time when, if Novartis is to be believed, it was unlikely that the '189 patent would ever issue.

The facts show that, on October 12, 2012, Novartis made a deliberate and calculated litigation decision to drop the '987 patent against Wockhardt. (*See* Opp'n, D.I. 135, at 3 and D.I. 53-1.) However, Novartis would have this Court disregard the facts in favor of the tale it has now constructed. Novartis would have this Court believe that it asserted the '987 patent against Wockhardt in the face of its belief that such an assertion was “nonsensical” and that “practical reality would make it impossible for Novartis to effectively enforce its legal rights under the '987 patent” until the '189 patent issued. (*See* Opp'n, D.I. 135, at 13.) Moreover, Novartis would have this Court believe that it made this choice, even though the '189 patent had been “bedeviled” by delays for over ten years.¹ (*See id.* at 12.)

¹ Although Novartis claims that '189 patent was “bedeviled” by delays, it was actually bedeviled by an inability to convince the PTO of the novelty of its alleged invention. (*See* Confoy Decl. at Ex. 2, Transaction History of the '189 patent (reflecting eight office actions and three notices of appeal).)

As this Court has stated, Novartis is “a very strong presence in the patent and pharmaceutical area.” (Mar. 1, 2013 TRO Hearing Tr. at 76:21-23.) As this Court also stated during the TRO proceedings, “it strains credibility” to accept as true the idea that Novartis had not considered the consequences of the issuance of the ’189 patent when it elected not to assert any claims from the ’987 patent against Wockhardt. (*Id.*) Thus, as evidenced by Novartis’s assertion of the ’987 patent, it was entirely practical for Novartis to choose to assert its legal rights regarding the ’987 patent prior to issuance of the ’189 patent. (*See* Compl., D.I. 1, ¶¶ 44-48.) Novartis reviewed Wockhardt’s noninfringement position and made a tactical, litigation decision not to assert any claims from the ’987 patent. Novartis’s change of heart cannot constitute good cause.

The record evidence shows that, although the ’189 patent had not issued, Novartis did not find it nonsensical or impractical to assert the ’987 patent against Wockhardt. The dropping and then reasserting of the ’987 patent is not in reaction to a change in *legal rights*, it is just another improper shift in the sands of Novartis’s litigation strategy.

2. The Record Does Not Support the Finding that Prior to the ’189 Patent Issuance Novartis Could Not Protect Zometa[®]

Novartis’s argument in support of the Magistrate Judge’s finding of good cause relies on a second fallacy, the suggestion that, prior to the issuance of the ’189 patent, Novartis had no patent protection for Zometa[®], leaving a loophole for

generics to exploit Reclast[®]. Novartis has listed the '241 patent in the FDA Orange Book as covering Zometa[®]. Thus, Novartis's claim that it had no patent protection for Zometa[®] is flatly contradicted by the record.

In its June 27, 2012 Compl., Novartis alleged that Wockhardt's ANDA No. 203989, an ANDA directed to Zometa[®], infringed the '241 patent. (*See* Complaint, D.I. 1, ¶¶ 39-43.) Moreover, Novartis has listed the '241 patent in the FDA's Orange Book as a patent with claims covering the Zometa[®] product. (*See* Confoy Decl. at Ex. 1.) Accordingly, it was not impractical for Novartis to protect its legal rights under the '987 patent because, contrary to Novartis's claims, Zometa[®] was in fact protected by the '241 patent.²

Once the fallacies in Novartis's argument are corrected, its tale of "good cause" and changed circumstances crumbles. Novartis has said that the '241 patent covers Wockhardt's generic Zometa[®] product. Accordingly the record cannot support Novartis's argument or the Magistrate Judge's finding that until the '189 patent issued Novartis was unable to protect its zoledronic acid products.

² If Novartis now maintains that the '241 patent does not cover Zometa[®], then the improper Orange Book listing should be withdrawn. Moreover, Novartis's complaint against Wockhardt, wherein it asserted that Wockhardt's ANDA for its generic Zometa[®] products would infringe the '241 patent, should be amended. Further, and in an effort to simplify the analysis for this appeal, Wockhardt would be willing to stipulate with Novartis that the '241 patent does not cover Wockhardt's generic Zometa[®] products.

B. The Magistrate Judge's Finding of Good Cause Is Contrary To Law

The Magistrate Judge's finding of good cause, premised on a change in the practicality of reasserting a patent for business reasons, is contrary to law. The Magistrate Judge, in fact, pointed out that "it is a bit unusual and really I don't find much support in this unique context and other cases." (May 21, 2013 Hearing Tr. at 23:14-16.) Courts have also explained that

while Rule 3.7 'is not a straitjacket into which litigants are locked from the moment their contentions are served' the '*modest* degree of flexibility' that the Rule provides must be viewed in the context of the Local Patent Rules' overarching goal of having the parties establish their contentions early in the litigation.

Janssen Pharm. Inc. v. Sandoz, Inc., C.A. No. 11-7247 (FLW) (D.N.J. Oct. 25, 2012) (D.I. 56 at 4) (internal citation omitted)(emphasis added).

"The [Local Patent R]ules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *TFH Publications, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010) (citing *Atmel Corp. v. Info. Storage Devices Inc.*, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998) (internal quotations omitted)). Moreover, "the philosophy behind amending [contentions] is decidedly conservative, and designed to prevent the shifting sands approach to claim construction." *Id.*

The Magistrate Judge's order flies in the face of the purpose of the Local Patent Rules. There is no precedent for finding good cause based on a change in business strategy – particularly, where, as here, that “strategy” is undercut by Novartis's own actions. *Novartis's legal rights to the '987 patent have not changed.* The Magistrate Judge's ruling opens the door to future litigants citing unsupported *business strategy* theories to substantively change the course of litigation, completely undermining the intent for amending contentions to be “decidedly conservative.”

The Magistrate Judge's finding of good cause is not only contrary to the record, but it is also contrary to law. Accordingly, this Court should reverse the Magistrate Judge's finding of good cause to amend the Asserted Claims.

C. Consolidation Does Not Give Novartis The Right To Amend Its Asserted Claims

1. Novartis's Decision to Assert the '987 Patent Against Other Defendants Does Not Support A Finding of Good Cause

Novartis argues that good cause exists simply because the Court will still be required to address the '987 patent with regards to other defendants. This argument is nonsensical. Novartis relies heavily on the fact that the Court will need to consider the '987 patent with regards to other defendants, however that has absolutely no impact on the fact that there was no good cause to reassert the '987 patent against *Wockhardt*. Nowhere in the Local Patent Rules does suing an

additional party create good cause. *See* L. Pat. R. 3.7. Even Novartis’s definition of good cause, however overbroad and inaccurate, as “the occurrence of an event relevant to the *merits* of a party’s claim that occurs after the deadline to disclose asserted claims” does not encompass filing a lawsuit against other parties. (Opp’n, D.I. 135, at 9 (emphasis added).)

Novartis’s attempt to justify its illogical position is similarly meritless. As Novartis has already admitted, stating that it “included the ’987 Patent in [the 2013 Case] against Wockhardt because of the ambiguity presented by Wockhardt’s intention to oppose Novartis’s proposed amendment to its Disclosure of Asserted Claims to add claims from the ’987 patent,” (13-cv-1028, D.I. 78 at 15), the reassertion of the ’987 patent is simply an end around of the Local Patent Rules. Such improper, duplicative reassertion of the ’987 patent should be barred.³ Suing

³ Novartis is incorrect in its assertion that Wockhardt’s pending motion to dismiss is moot. As Wockhardt explained in its pending motion to dismiss, upon final judgment in this case, Novartis will be barred from continually reasserting the same claims against Wockhardt based on actual sales. *See Huck ex rel. Sea Air Shuttle Corp. v. Dawson*, 106 F.3d 45, 49 (3d Cir. 1997) (holding res judicata barred assertion of claims in second suit where claims could have been properly raised and litigated by plaintiff in first suit but were not and plaintiff’s motion to amend complaint in first suit to include those claims was denied); *Nilsen v. Moss Point*, 701 F.2d 556, 560, 563 (5th Cir. 1983) (“[R]es judicata ... bars all claims that were or could have been advanced in support of the cause of action on the occasion of its former adjudication” and “theories which were the subject of an untimely motion to amend, filed in the earlier action, ‘could have been brought’ there.”); (*see also* Wockhardt’s Reply Br. in Support of its Motion to Dismiss, 13-cv-1028 D.I. 237, at 10-13.)

other parties on the '987 patent does not support a finding of good cause to reassert the '987 patent against Wockhardt.

2. Consolidation Is Irrelevant To A Good Cause Analysis

Novartis's attempt to characterize consolidation as an aspect of good cause, rather than prejudice, is based on a mischaracterization of the Magistrate Judge's understanding of the effect of consolidation. The Magistrate Judge stated her reasoning for finding good cause and further explained that if

there wasn't a consolidation motion, there weren't other cases that had to be coordinated, the Court may have looked at this case differently.

But I'd be strained to say in light of the fact that *I'm inclined to consolidate* that there would be any real litigation *prejudice* here in terms of scheduling.

(May 21, 2013 Hearing Tr. 24:3-9 (emphasis added).) More importantly, the Magistrate Judge specifically agreed that consolidation does not go to the issue of good cause:

Mr. Zimmerman: And [consolidation] goes to the prejudice front. But it still doesn't get to the threshold issue of good cause.

The Court: Right.

(May 21, 2013 Hearing Tr. 18:22-24.)

Novartis attempts to justify the conflation of "good cause" and prejudice by twisting consolidation into an aspect of good cause. However, as the Magistrate

Judge agreed on the record, consolidation goes to prejudice, not to the threshold issue of good cause.

3. Applying Consolidation To Good Cause Instead of Prejudice Is Contrary To Law

As made clear on the record, consolidation is relevant only to prejudice. (See May 21, 2013 Hearing Tr. 18:18-24.) Novartis, however, argues that the Magistrate Judge considered consolidation in her good cause analysis. (Opp’n, D.I. 135, at 2, 8, 16.) Specifically, Novartis argues that “Judge Arleo independently concluded that there was good cause for the amendment, on the basis of ... the changes to the case schedule that would follow from consolidation.” (*Id.* at 16.) Accepting Novartis’s argument as true, that the Magistrate Judge based her good cause finding on the fact that she was ordering consolidation, then the ruling is contrary to law.

The Local Patent Rules state that “[a]mendment of ... disclosures ... may be made only by order of the Court upon a timely application and showing of good cause.” L. Pat. R. 3.7. Novartis incorrectly states that “the Court may permit amendment of ‘any contentions [or] disclosure’ ‘absent *undue* prejudice to the adverse party.’” (Opp’n, D.I. 135, at 14.) Though Novartis would prefer to interpret the Local Patent Rules to allow it to amend its contentions at will and merely upon a showing of no undue prejudice, that is not the case. Rather, Novartis must first meet the threshold requirement of showing “timely application

and good cause.” *See AstraZeneca AB v. Hanmi USA, Inc.*, C.A. No. 11-760 JAP, 2013 WL 264609 (D.N.J. Jan. 23, 2013 (“[T]he Court finds that there is good cause, absent prejudice to Hanmi, to permit [amendment].”); *see also* L. Pat. R. 3.7 (“Nonexhaustive examples of circumstances that may, absent undue prejudice, support a finding of good cause.”). Prejudice to Wockhardt is irrelevant, unless Novartis can demonstrate good cause, which it has failed to show. *See O2 Micro Int’l Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1368 (Fed. Cir. 2006) (Finding no need to consider the prejudice to the adverse party, after concluding that a party did not act diligently). Accepting Novartis’s argument as true, then the Magistrate Judge’s ruling is contrary to law and should be reversed.

D. The Magistrate Judge Committed Clear Error by Ignoring the Prejudice to Wockhardt

Because Novartis has failed to show good cause, the Magistrate Judge need not have even considered whether there was undue prejudice to Wockhardt. However, even if the Magistrate Judge had properly found good cause, she erred by failing to consider the undue prejudice to Wockhardt.

As explained in detail in Wockhardt’s opening appeal brief, Wockhardt would be severely prejudiced if Novartis is permitted to reassert the ’987 patent after failing to assert claims from that patent when required by the Local Patent Rules.

III. CONCLUSION

For the reasons set forth above, Wockhardt respectfully requests that the Court reverse the Magistrate Judge's Order, and deny Novartis's request to amend the Disclosure of Asserted Claims to assert claims from the '987 patent.

Respectfully submitted,

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